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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,361	07/26/2001	George M. Grass	109904-00015	6311

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EXAMINER	
BRUSCA, JOHN S	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,361	GRASS ET AL.	
	Examiner	Art Unit	
	John S. Brusca	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52,80-121 and 137-231* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-52,80-121 and 137-231* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/14/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is a non-final rejection because it contains new grounds of rejection under 35 U.S.C. § 102(f) not necessitated by the applicant's amendment.

Priority

2. The application now properly claims the benefit of U.S. Provisional Applications 60/100224, 60/100290, 60/109234, and 60/109232 in view of the amendment to the specification filed 14 February 2005.

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a non-provisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

In the amendment to the specification filed 14 February 2005, no relationship to the non-provisional U.S. Applications is stated.

Information Disclosure Statement

4. The missing references from the Information Disclosure Statement filed 17 July 2001 have been provided by the applicants in the response filed 14 February 2005. Except as noted, the references have been listed on the signed list of references attached to this Office action.

Terminal Disclaimer

5. The terminal disclaimer filed on 14 February 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No.. 6,647,358 has been reviewed and is accepted. The terminal disclaimer has been recorded.

6. In the cover letters and response filed 14 February 2005 two terminal disclaimer filings are mentioned, however a terminal disclaimer for U.S. Patent No. 6,542,858 has not been entered in the instant application file.

7. It is further noted that multiple patents and applications may be disclaimed in a single terminal disclaimer for which only a single fee is due.

Claim Objections

8. The objection to claims 22 and 23 in the Office action mailed 12 August 2004 is withdrawn in view of the amendment filed 14 February 2005.

Claim Rejections - 35 USC § 112

9. The rejection of claims 1, 80, and 81 under 35 U.S.C. 112, second paragraph in the Office action mailed 12 August 2004 is withdrawn in view of the amendment to the claims filed 14 February 2005.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 2-21, 106-114, 184-197, and 199-215 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims have a limitation of a regional correlation that is adjusted by analysis of data of a plurality of compounds. The specification mentions at various places an optional regional correlation parameter without further stating that the regional correlation parameter may be adjusted by analysis of data of a plurality of compounds.

Claim Rejections - 35 USC § 102

12. The rejection of claims 1-53, 80-121, and 137-199 under 35 U.S.C. 102(b) as being anticipated by Grass in the Office action mailed 12 August 2004 is withdrawn in view of the amendment to the claims filed 14 February 2005.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-53, 80-121, and 137-231 rejected under 35 U.S.C. 103(a) as being unpatentable over Grass (reference BW in the Information Disclosure Statement filed 17 July 2001) in view of Gex-Fabry et al. (reference BT in the Information Disclosure Statement filed 17 July 2001).

The claims are drawn to a method of using a pharmacokinetic model to predict a pharmacokinetic property of a compound in a second anatomical location by use of a

pharmacokinetic property of a test compound in a first anatomical location. In some embodiments parameters such as a selected adjustment parameter or a regional correlation parameter are refined by use of data from a plurality of compounds. In some embodiments the claims are drawn to computers or programs that execute the method. In some embodiments the model uses in vitro data, log functions, programs and computers using if..then statements, models comprising absorption models in the gastrointestinal tract, differential equations, and models that comprise properties of two different species of animal or tissues or cells.

Grass et al. shows in the abstract and throughout pharmacokinetic models that predict behavior of compounds in animals. Grass shows use of in vivo, in situ, and in vitro pharmacokinetic data of compounds on pages 202-205, models with log functions on page 205, computers and programs that execute the method on page 207, programs with if..then statements on page 207. models of absorption in multiple segments of the gastrointestinal tract on page 207 and throughout, models using differential equations on page 208, models that compare behavior of different species of animals on pages 209-211, and models that use behavior of tissue and in vitro cells on page 209-211. Grass shows in figures 19 and 20 that the models provide accurate predictions of absorption of two different compounds in the gastrointestinal tract. Grass et al. does not explicitly show fitting of pharmacokinetic data of multiple compounds to derive parameters for use in the model.

Gex-Fabry et al. reviews computer models of pharmacokinetic behavior of compounds in anatomical sites. Gex-Fabry et al. shows on page 513 and beyond the use of data to refine parameter values that are used in computer pharmacokinetic models.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method and computer models of Grass et al. by refining the parameters used in the model by use of data from a plurality of compounds because Gex-Fabry et al. shows such refinement is useful to obtain more accurate parameters.

Double Patenting

17. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would be obvious over, the reference claim(s). see, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-53, 80-86, 88-101, 104-121, 137-147, 149-163, and 165-231 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-82 of U.S. Patent No. 6,542,858. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of U.S. Patent No. 6,542,858 are drawn to species of the instant claims.

Claims 1-53, 80-86, 88-101, 104-121, 137-147, 149-163, and 165-231 are directed to an invention not patentably distinct from claims 1-82 of commonly assigned U. S. Patent No. 6,542,858. Specifically, claims of U.S. Patent No. 6,542,858 are drawn to species of the instant claims.

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

21. Claims 1-53, 80-114, and 137-231 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

For the reasons discussed above, it is apparent that U.S. Patent No. 6,542,858 contains claimed subject matter that is not patentably distinct from instant claims 1-53, 80-114, and 137-231. Because the inventive entity of U.S. Patent No. 6,542,858 is different from the instant application, a rejection is appropriate under 35 U.S.C. 102(f). This rejection could be overcome by amendment of the appropriate claims so that the claims are patentably distinct, or by filing a declaration stating the inventive entity for the commonly claimed subject matter is identical.

22. Claims 1, 22-53, 80-105, 137-183, 198, and 216-231 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

U.S. Patent No. 6,647,358 contains claimed subject matter that is not patentably distinct from instant claims 1, 22-53, 80-105, 137-183, 198, and 216-231. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of U.S. Patent No. 6,647,358 are drawn to species of the instant claims. Because the inventive entity of U.S. Patent No. 6,647,358 is different from the instant application, a rejection is appropriate under 35 U.S.C. 102(f). This rejection could be overcome by amendment of the appropriate claims so that the claims are patentably distinct, or by filing a declaration stating the inventive entity for the commonly claimed subject matter is identical.

Conclusion

23. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is

(866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199.Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714: The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD. can be reached on 571 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

J.S. Brusca 15 April 2005

John S. Brusca

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